

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2017.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-468

Trade Name: Stafac® and Bio-Cox®
Ingredients: Virginiamycin and salinomycin sodium
Sponsor: Phibro Animal Health Corp.
Approval Date: January 13, 2017
Status: VFD
Route: Oral, in feed
Species: Broiler and fryer chickens
Drug Form: Type A medicated article
Concentration: Virginiamycin: 10, 20, 50, or 227 g/lb
Salinomycin: 30 or 60 g/lb
Indications: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

NADA Number: 141-469

Trade Name: Stafac® and AMPROL®
Ingredients: Virginiamycin and amprolium
Sponsor: Phibro Animal Health Corp.
Approval Date: January 13, 2017
Status: VFD
Route: Oral, in feed
Species: Broiler chickens
Drug Form: Type A medicated article
Concentration: Virginiamycin: 10, 20, 50, or 227 g/lb
Amprolium: 25% amprolium
Indications: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *E. tenella* in broiler chickens.
For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis where immunity to coccidiosis is not desired in broiler chickens.

NADA Number: 141-470

Trade Name: Stafac® and Avatec®
Ingredients: Virginiamycin and lasalocid sodium
Sponsor: Phibro Animal Health Corp.
Approval Date: January 13, 2017
Status: VFD
Route: Oral, in feed
Species: Broiler and fryer Chickens
Drug Form: Type A medicated article
Concentration: Virginiamycin: 10, 20, 50, or 227 g/lb. virginiamycin
Lasalocid sodium: 90.7 g/lb. lasalocid sodium
Indications: For the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

NADA Number: 141-472

Trade Name: Clinacox® and Stafac®
Ingredients: Diclazuril and virginiamycin
Sponsor: Huvepharma EOOD

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Approval Date: January 13, 2017
Status: VFD
Route: Oral, in feed
Species: Broiler and fryer Chickens
Drug Form: Type A medicated article
Concentration: Diclazuril: 0.2% diclazuril
Virginiamycin: 10, 20, 50, or 227 g/lb. virginiamycin
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis (mivati)*, and *E. maxima*. Because diclazuril is effective against *E. maxima* late in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with *E. maxima*. For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin in broiler chickens.

Medical Gases

The following request for a certification of a medical gas as a designated medical gas was deemed to be granted:

Application Number	Sponsor Name	Medical Gas
141-477	Matheson Tri-Gas, Inc.	Nitrous Oxide, USP

Sponsor Change

(A)NADA Numbers: 200-481, 141-420

Previous Sponsor: Ceva Sante Animale
New Sponsor: Cross Vetpharm Group Ltd.
Drug Labeler Code: 061623

(A)NADA Number: 200-587

Previous Sponsor: Cross Vetpharm Group Ltd.
New Sponsor: Ceva Sante Animale
Drug Labeler Code: 013744

(A)NADA Numbers: 141-099, 141-220, N-141-247

Previous Sponsor: Boehringer Ingelheim Vetmedica, Inc.
New Sponsor: Bayer HealthCare LLC, Animal Health Division
Drug Labeler Code: 000859

(A)NADA Number: 141-272

Previous Sponsor: Nexcyon Pharmaceuticals, Inc.
New Sponsor: Pegasus Laboratories, Inc.
Drug Labeler Code: 055246

Suitability Petitions

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2017.

Number: 16-P-3427

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 16, 2016
Action: Approved
Action Date: January 12, 2017
Description: The petitioner requests to file an ANADA for a generic deracoxib tablet for use in dogs that differs from the pioneer product, Derramaxx® (deracoxib) chewable tablet, sponsored by Elanco US, Inc. under 141-203. The proposed change is in dosage form. The RLNAD is approved as a compressed tablet. The proposed change is for a soft chewable tablet.

Number: 16-P-3428

Petitioner: Felix Pharmaceuticals Pvt. Ltd.
Date Filed: October 17, 2016
Action: Approved
Action Date: January 10, 2017
Description: The petitioner requests to file an ANADA for a generic cefpodoxime tablet for use in dogs that differs from the pioneer product, Simplicef® (cefpodoxime) tablet, sponsored by Zoetis Inc. under 141-232. The proposed change is in dosage form. The RLNAD is approved as a compressed, film-coated tablet. The proposed change is for a soft chewable tablet.